

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

---

IN RE BENDAMUSTINE CONSOLIDATED  
CASES

---

)  
)  
)  
) C.A. No. 13-2046-GMS (consolidated)  
)  
)  
)

**PLAINTIFF CEPHALON, INC.'S ANSWERING BRIEF IN OPPOSITION TO  
DEFENDANTS SAGENT, DRL, UMAN AND INNOPHARMA'S  
RULE 12(C) MOTION FOR JUDGMENT ON THE PLEADINGS**

**OF COUNSEL:**

David M. Hashmall  
Calvin E. Wingfield Jr.  
Jonathan A. Auerbach  
Timothy J. Rousseau  
Joshua A. Whitehill  
**GOODWIN PROCTER LLP**  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018-1405  
(212) 813-8800

Paul F. Ware  
Daryl L. Wiesen  
Emily L. Rapalino  
Nicholas K. Mitrokostas  
**GOODWIN PROCTER LLP**  
Exchange Place  
Boston, MA 02109  
(617) 570-1000

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Stephanie E. O'Byrne (No. 4446)  
**SHAW KELLER LLP**  
300 Delaware Ave., Suite 1120  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com

Stephen B. Brauerman (No. 4952)  
Vanessa R. Tiradentes (No. 5398)  
Sara E. Bussiere (No. 5725)  
**BAYARD, P.A.**  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19801  
(302) 655-5000  
sbrauerman@bayardlaw.com  
vtiradentes@bayardlaw.com  
sbussiere@bayardlaw.com

*Attorneys for Plaintiff Cephalon, Inc.*

Dated: January 9, 2015

## TABLE OF CONTENTS

I.....INTRODUCTION .....	1
II. ....BACKGROUND AND STATEMENT OF FACTS .....	2
III. ....LEGAL STANDARDS .....	3
IV.....DEFENDANTS’ MOTION IS A PROCEDURALLY IMPROPER, THINLY DISGUISED MOTION FOR SUMMARY JUDGMENT .....	4
V. ....DEFENDANTS ARE NOT ENTITLED TO JUDGMENT ON THE PLEADINGS ON THE ISSUE OF NON-INFRINGEMENT.....	5
A. ....Cephalon Has Alleged Sufficient Facts To Survive Defendants’ Motion.....	6
B. ....Defendants’ Motion Improperly Seeks Factual Infringement Determinations.....	7
C. ....The Disclosure-Dedication Rule Does Not Preclude a Finding that Defendants Infringe the ’190 Patent and/or the ’863 Patent Under the Doctrine of Equivalents .....	9
VI.....CONCLUSION.....	12

## TABLE OF AUTHORITIES

	Page(s)
<b>CASES</b>	
<i>Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.</i> , 988 F.2d 1157 (Fed. Cir. 1993).....	6
<i>Cumberland Pharm., Inc. v. InnoPharma, Inc.</i> , No. 12-618-LPS, 2013 WL 5945794 (D. Del. Nov. 1, 2013).....	8
<i>Cumberland Pharm., Inc. v. Sagent Agila LLC</i> , No. 12-825-LPS, 2013 WL 5913742 (D. Del. Nov. 1, 2013) .....	8
<i>DR Sys., Inc. v. Avreo, Inc.</i> , No. 11-cv-0932 BEN (WVG), 2011 WL 4850171 (S.D. Cal. Oct. 12, 2011).....	4
<i>Ferrell v. Cmty. Mgmt. Servs., LLC</i> , C.A. No. 10-205-SLR, 2011 WL 1750452 (D. Del. May 6, 2011) .....	4, 7
<i>Fujitsu Ltd. v. Belkin Int’l, Inc.</i> , 782 F. Supp. 2d 868 (N.D. Cal. 2011) .....	4
<i>Genzyme Corp. v. Anchen Pharmaceuticals, Inc.</i> , Case No. 10-cv-00512-GMS, D.I. 50 (D. Del. Oct. 31, 2011) .....	8
<i>Graver Tank &amp; Mfg. Co. v. Linde Air Prods. Co.</i> , 339 U.S. 605 (1950).....	9
<i>In re Burlington Coat Factory Sec. Litig.</i> , 114 F.3d 1410 (3d Cir. 1997).....	4, 5
<i>In re Rockefeller Ctr. Props., Inc. Sec. Litig.</i> , 184 F.3d 280 (3d Cir. 1999).....	4
<i>Janssen Products, L.P. v. Lupin Ltd.</i> , Case No. 10-5954 (WHW), 2014 U.S. Dist. LEXIS 155248 (D.N.J. Mar. 12, 2014).....	10, 11
<i>Johnson &amp; Johnston Assocs. Inc. v. R.E. Serv. Co.</i> , 285 F.3d 1046 (Fed. Cir. 2002) (en banc).....	9
<i>Mark IV Indus. Corp. v. Transcore, L.P.</i> , C.A. No. 09-418-GMS, 2009 WL 4828661 (D. Del. Dec. 2, 2009).....	6
<i>Maxwell v. J. Baker, Inc.</i> , 86 F.3d 1098 (Fed. Cir. 1996).....	10

<i>Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.</i> , 203 F.3d 790 (Fed. Cir. 2000).....	6
<i>Rainer v. Rispoli</i> , C.A. No. 10-498-GMS, 2012 WL 752371(D. Del. Mar. 6, 2012).....	3
<i>Rosby Corp. v. Stoughton Trailers, Inc.</i> , Case No. 95-cv-0511, 2003 U.S. Dist. LEXIS 17034 (N.D. Ill. Sept. 24, 2003) .....	11
<i>Rosenau v. Unifund Corp.</i> , 539 F.3d 218 (3d Cir. 2008).....	3
<i>Shamrock Holdings. v. Arenson</i> , 456 F. Supp. 2d 599 (D. Del. 2006).....	3
<i>Southmark Prime Plus, L.P. v. Falzone</i> , 776 F. Supp. 888 (D. Del. 1991).....	3
<i>Tarkus Imaging, Inc. v. Adobe Sys., Inc.</i> , No. 10-63-LPS, 2011 WL 1557930 (D. Del. Apr. 21, 2011) .....	7
<i>Tech. Innovations, LLC v. Amazon.com, Inc.</i> , C.A. No. 11-690-SLR, 2012 WL 1441300 (D. Del. Apr. 25, 2012) .....	7
<i>TQP Dev., LLC v. Ticketmaster Entm’t, Inc.</i> , C.A. No. 2:09-CV-279-TJW, 2010 WL 1740927 (E.D. Tex. Apr. 29, 2010) .....	4
<i>Turbe v. Gov’t of Virgin Islands</i> , 938 F.2d 427 (3d Cir. 1991).....	4, 7
<i>Venetec Int’l, Inc. v. Nexus Med., LLC</i> , 541 F. Supp. 2d 612 (D. Del. 2008).....	3
<i>Walker Digital, LLC v. Facebook, Inc.</i> , 852 F. Supp. 2d 559 (D. Del. 2012).....	7

#### **OTHER AUTHORITIES**

FED. R. CIV. P. 8(a).....	6
FED. R. CIV. P. 12(c) .....	3
FED. R. CIV. P. 12(d) .....	4, 5

## **I. INTRODUCTION**

The Court should deny the motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) for non-infringement of United States Patent Nos. 8,436,190 (“the ’190 patent”) and 8,609,863 (“the ’863 patent”) filed by Defendants Sagent Pharmaceutical, Inc.; Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc.; Uman Pharma, Inc.; and InnoPharma Inc. (together “Defendants”) (D.I. 58). While styled as one for judgment “on the pleadings,” Defendants’ motion is not based at all on Cephalon’s pleadings, which are plainly sufficient to allege counts of infringement of both the ’190 patent and the ’863 patent.

Defendants’ motion is, in substance and practice, a motion for summary judgment of non-infringement. But the issue of infringement is undoubtedly factual, and resolution of that issue would require the Court to engage in an analysis of Defendants’ products as compared to the claimed subject matter before any meaningful fact discovery has taken place, and before any expert discovery at all. It is exactly for that reason that this Court strongly disfavors the filing of motions for summary judgment, particularly at this stage of the litigation, and ordered Defendants not to file any such motions in this case. Defendants’ motion, filed just weeks after the Court entered an order prohibiting the filing of summary judgment motions, is a thinly veiled attempt to avoid this Court’s scheduling order.

Whether Defendants’ ANDA products infringe the ’190 patent and the ’863 patent should not and cannot be decided on the pleadings. Even if the Court were to reach the merits of the motion, however, it should still be denied. Defendants infringe the ’190 patent and the ’863 patent under the doctrine of equivalents because, at least, the evidence at trial will demonstrate that the solvent systems used in Defendants’ respective ANDA products are insubstantially different from the solvent systems claimed in the ’190 and ’863 patents. The solvent systems used in Defendants’ respective ANDA products also perform substantially the same function in

substantially the same way to achieve substantially the same result as the solvent systems claimed in the patents. Defendants' effort to get around that critical truth by manufacturing a "legal issue" is inadequate, as Cephalon did not dedicate to the public the use of the identified solvent systems during prosecution of the '190 patent and the '863 patent.

Accordingly, for at least these reasons, Defendants' motion for judgment of non-infringement under Rule 12(c) should be denied.

## **II. BACKGROUND AND STATEMENT OF FACTS**

This is a Hatch-Waxman patent infringement case between Cephalon and Defendants involving Cephalon's innovative treatment for chronic lymphocytic leukemia and indolent non-Hodgkin's lymphoma, which is marketed as TREANDA<sup>®</sup>. The '190 patent and the '863 patent, which are assigned to Cephalon, are listed for TREANDA<sup>®</sup> in FDA's Orange Book.

Defendants notified Cephalon that they had filed ANDAs containing Paragraph IV certifications seeking approval to market their respective generic bendamustine products prior to the expiration of the '190 patent and the '863 patent. After reviewing materials produced by Defendants pursuant to Offers of Confidential Access, Cephalon asserted the '190 patent and/or the '863 patent against Defendants' ANDA products because those products infringe at least one claim in each patent. Defendants' ANDA products use formulation constituents that are the same as or insubstantially different from those in the formulations claimed in those patents.

On October 30, 2014, the Court held a Rule 16(b) Scheduling Conference in these consolidated actions. On November 12, 2014, the parties submitted their proposed scheduling order, which among other things, identified the parties' dispute relating to the filing of motions for summary judgment. (*See* D.I. 37-1 (cover letter accompanying the parties' [Proposed] Scheduling Order).) Defendants specifically requested leave to insert language in the Scheduling Order allowing Defendants to seek permission to file motions for summary judgment. Cephalon

did not believe any deviation from the Court's normal practice was warranted and did not join Defendants' request. This Court's November 14, 2014 Oral Order explicitly prohibited the filing of summary judgment motions in these actions, stating "The defendant's request to include standard form summary judgment procedures is denied. This section shall be stricken from the proposed case management order." Less than a month later, Defendants filed the present motion. The motion was filed prior to any Defendants' completing the substantial production of their documents, prior to the taking of any fact depositions, and while the parties are in the process of briefing issues of claim construction.

### III. LEGAL STANDARDS

Pursuant to Rule 12(c), "[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings." FED. R. CIV. P. 12(c). Judgment on the pleadings will not be granted unless the moving party clearly establishes that no material issue of fact remains to be resolved and that the party is entitled to judgment as a matter of law. *Rosenau v. Unifund Corp.*, 539 F.3d 218, 221 (3d Cir. 2008); *Shamrock Holdings. v. Arenson*, 456 F. Supp. 2d 599, 604 (D. Del. 2006), citing *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988); *see also Venetec Int'l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008). Because Rule 12(c) "provides for the summary disposition of a party's claims on the merits before discovery, such motions are disfavored." *Southmark Prime Plus, L.P. v. Falzone*, 776 F. Supp. 888, 891 (D. Del. 1991).

Because Defendants' motion is based on an allegation that Cephalon failed to state a claim for patent infringement (*see* Defs. Br. at 3–7), Defendants' motion for judgment on the pleadings under Rule 12(c) is governed by the same standards that apply to a motion to dismiss made under Rule 12(b)(6). *See Rainer v. Rispoli*, C.A. No. 10-498-GMS, 2012 WL 752371, at \*2 (D. Del. Mar. 6, 2012) (quoting *Spruill v. Gillis*, 372 F.3d 218, 223 n. 2 (3d Cir. 2004) (noting

that “[t]here is no material difference in the applicable legal standards” between Rule 12(c) and Rule 12(b)(6)); *Ferrell v. Cmty. Mgmt. Servs., LLC*, C.A. No. 10-205-SLR, 2011 WL 1750452, at \*1 (D. Del. May 6, 2011), citing *Revell v. Port Auth. of N.Y. & N.J.*, 598 F.3d 128, 134 (3d Cir. 2010). Under that standard, the Court must accept all the factual allegations in Cephalon’s complaint as true and take them in the light most favorable to Cephalon. *See Turbe v. Gov’t of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Ferrell*, 2011 WL 1750452 at \*1.

In considering a motion under Rule 12(b)(6), the Court may consider only the pleadings and documents “integral to or explicitly relied upon in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997). If, however, the Court decides to consider documents extraneous to the pleadings, such consideration converts the motion into one for summary judgment. Fed. R. Civ. P. 12(d). In that event, the parties must be given a reasonable opportunity to present all the material that is pertinent to the motion. *Id.*; *see In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 184 F.3d 280, 287–88 (3d Cir. 1999). Determination of infringement is strongly disfavored on a motion to dismiss. *See, e.g., Fujitsu Ltd. v. Belkin Int’l, Inc.*, 782 F. Supp. 2d 868, 890 (N.D. Cal. 2011) (“infringement analysis should not be resolved on a motion to dismiss”); *DR Sys., Inc. v. Avreo, Inc.*, No. 11-cv-0932 BEN (WVG), 2011 WL 4850171, at \*2 (S.D. Cal. Oct. 12, 2011) (“issue[s] of ... infringement [are] not properly considered in a 12(b)(6) motion”); *TQP Dev., LLC v. Ticketmaster Entm’t, Inc.*, C.A. No. 2:09-CV-279-TJW, 2010 WL 1740927, at \*2 (E.D. Tex. Apr. 29, 2010) (declining to find non-infringement as a matter of law “[w]ithout any discovery or a claim construction”).

#### **IV. DEFENDANTS’ MOTION IS A PROCEDURALLY IMPROPER, THINLY DISGUISED MOTION FOR SUMMARY JUDGMENT**

Defendants’ motion seeks judgment of non-infringement as a matter of law by relying upon materials other than what is stated in the allegations of Cephalon’s pleadings. Indeed,



Defendants cite to a number of documents, such as excerpts from their respective ANDAs, that cannot be properly considered in the context of a Rule 12(c) motion for judgment on the pleadings or a Rule 12(b)(6) motion to dismiss because none of those documents were attached to the complaints or are “integral to or explicitly relied upon in the [C]omplaint.” For example, while the details of Defendants’ ANDAs are critical to the motion, those details are found nowhere in the pleadings. Defendants’ reliance on such materials only proves that their motion is not really one for judgment on the pleadings.

Because those documents cannot properly be considered under Rule 12(c) or Rule 12(b)(6), consideration of Defendants’ motion requires converting the motion to one for summary judgment under Rule 56. *See* FED. R. CIV. P. 12(d); *Burlington*, 114 F.3d at 1426. Such a motion, however, flatly violates this Court’s November 14, 2014 Order—issued just three weeks prior to the filing of this motion—that struck from the Scheduling Order in this case procedures allowing for the filing of summary judgment motions. Defendants’ motion, relying on documents outside the pleadings, directly contravenes the Court’s order preventing the filing of motions for summary judgment. For this reason alone, the Court should deny Defendants’ motion.

#### **V. DEFENDANTS ARE NOT ENTITLED TO JUDGMENT ON THE PLEADINGS ON THE ISSUE OF NON-INFRINGEMENT**

Even if the Court decides to consider the merits of Defendants’ motion, the Court should deny the motion because (1) the Complaint sufficiently alleges facts to support a claim of patent infringement, (2) Defendants’ motion improperly asks this Court to resolve factual issues and make infringement determinations, and (3) Cephalon is not barred from asserting the doctrine of equivalents with respect to the ’190 patent and the ’863 patent.<sup>1</sup>

---

<sup>1</sup> The Court also should deny Defendants’ motion pursuant to Federal Rule of Civil Procedure

**A. Cephalon Has Alleged Sufficient Facts To Survive Defendants' Motion**

To survive a motion to dismiss, a patentee need only plead facts sufficient to place the alleged infringer on notice of the infringing acts and the claim for relief. *Phonometrics, Inc. v. Hospitality Franchise Sys., Inc.*, 203 F.3d 790, 794 (Fed. Cir. 2000) (reversing dismissal of patent infringement case where the complaint met notice-pleading requirements). A complaint contains enough detail for a defendant to answer and thus meets the requirements of notice pleading under the Federal Rules of Civil Procedure when it: (1) alleges ownership of and identifies the patent-in-suit; (2) names the defendant; (3) describes the means by which the defendant allegedly infringes; and (4) points to specific sections of the patent code at issue. *Mark IV Indus. Corp. v. Transcore, L.P.*, C.A. No. 09-418-GMS, 2009 WL 4828661, at \*3 (D. Del. Dec. 2, 2009) (denying Rule 12(b)(6) motion to dismiss patent infringement claim and quoting *Phonometrics*); FED. R. CIV. P. 8(a). “[D]ismissal is improper unless there is no reasonable view of the facts which could support the claim.” *Advanced Cardiovascular Sys., Inc. v. SciMed Life Sys., Inc.*, 988 F.2d 1157, 1160–61 (Fed. Cir. 1993) (vacating dismissal of patent infringement claim to allow patentee opportunity to show sufficient evidence to support his case).

Cephalon’s complaints amply meet this standard. They allege subject matter and personal jurisdiction, ownership of each asserted patent and its date of issuance, name the defendants, cite the patents that were allegedly infringed, describe the means by which defendants infringe the asserted patents, and point to specific sections of the patent laws that are at issue. (D.I. 1 at ¶¶ 3, 7–8, 14, 16, 52–74 in C.A. No. 13-2081-GMS (InnoPharma); D.I. 1 at

---

56(d) because responding to the merits of Defendants’ motion would require Cephalon to present facts about the equivalence of Defendants’ solvent systems with those recited in the claims of the ’190 patent and the ’863 patent, which Cephalon will develop through fact discovery (set to be completed on April 17, 2015) and expert discovery.

¶¶ 3–6, 9–12, 19–21, 57–79 in C.A. No. 13-2082-GMS (DRL); D.I. 1 at ¶¶ 3–6, 9–12, 14, 16, 29–51 in C.A. No. 14-334-GMS (DRL); D.I. 24 at ¶ 3, 6, 13–15, 56–78 in C.A. No. 14-568-GMS (Uman); D.I. 1 at ¶¶ 3, 6–7, 9–11, 24–46 in C.A. No. 14-590-GMS (InnoPharma); D.I. 1 at ¶¶ 2, 8–9, 16–25, 68–113 in C.A. No. 14-1116-GMS (Sagent).) Indeed, Defendants do not dispute that the allegations in Cephalon’s complaints against them are sufficient, which is the only legally relevant issue. *See, e.g., Tarkus Imaging, Inc. v. Adobe Sys., Inc.*, No. 10-63-LPS, 2011 WL 1557930, at \*3 (D. Del. Apr. 21, 2011) (denying motion to dismiss because infringement was at least plausible accepting the allegations in the complaint as true); *Tech. Innovations, LLC v. Amazon.com, Inc.*, C.A. No. 11–690–SLR, 2012 WL 1441300, at \*2 (D. Del. Apr. 25, 2012) (denying motion to dismiss where defendant argued that patent-in-suit could not cover Amazon’s Kindle); *Walker Digital, LLC v. Facebook, Inc.*, 852 F. Supp. 2d 559, 562–63 (D. Del. 2012) (denying motion to dismiss where defendant argued that the patent-in-suit “plainly” was not infringed where complaint was legally sufficient on its face). Because Cephalon’s allegations are plainly sufficient to plead a claim of infringement with respect to each of the Defendants’ ANDA products, Defendants’ motion should be denied.

#### **B. Defendants’ Motion Improperly Seeks Factual Infringement Determinations**

By their motion, Defendants improperly ask the Court to look beyond the four corners of the complaints and resolve factual disputes to conclude that under no set of facts could Defendants’ proposed ANDA products infringe the ’190 patent and the ’863 patent. Even if the Court were to entertain Defendants’ request to conduct an infringement analysis at this stage, Cephalon’s complaints allege that Defendants infringe the ’190 patent and the ’863 patent. For the purposes of Defendants’ motion, the Court must accept those factual allegations in Cephalon’s complaints as true and take them in the light most favorable to Cephalon. *See Turbe*, 938 F.2d at 428; *Ferrell*, 2011 WL 1750452 at \*1. Specifically, Defendants infringe the ’190

patent and the '863 patent under the doctrine of equivalents because the solvent systems used in Defendants' ANDA products<sup>2</sup> are equivalent to the solvent system claimed in the '190 patent and the '863 patent in all relevant respects. For example, the solvent systems used in Defendants' ANDA products are insubstantially different from the solvent systems recited in the '190 patent and the '863 patent. The solvent systems used in Defendants' ANDA products also perform substantially the same function in substantially the same way to achieve substantially the same result as the solvent systems claimed in the patents. All of these facts will be proven at trial, and Defendants cannot and do not refute them (indeed, they represented to FDA that their generic products are equivalent to TREANDA<sup>®</sup>, which uses tertiary-butyl alcohol). At the very least, the equivalence of these systems is a question of fact that must be determined after the completion of fact and expert discovery.

Further, Defendants incorrectly assert (D.I. 58 n.2) that *Genzyme Corp. v. Anchen Pharmaceuticals, Inc.*, Case No. 10-cv-00512-GMS, D.I. 50 (D. Del. Oct. 31, 2011), *Cumberland Pharm., Inc. v. InnoPharma, Inc.*, No. 12-618-LPS, 2013 WL 5945794 (D. Del. Nov. 1, 2013) or *Cumberland Pharm., Inc. v. Sagent Agila LLC*, No. 12-825-LPS, 2013 WL 5913742 (D. Del. Nov. 1, 2013) supports their position that judgment on the pleadings is appropriate here. *Genzyme* and the two *Cumberland* cases, however, are easily distinguishable from this case. In those cases, the plaintiff admitted in the pleadings the very fact that the Court relied on in granting the motion for judgment on the pleadings. (*Genzyme*, D.I. 50 at 1–2); *Cumberland*, 2013 WL 5945794, \*2; *Cumberland*, WL 5913742, \*2. Unlike in *Genzyme* and the

---

<sup>2</sup> The details of Defendants' ANDA products, including the solvent systems used by each, are nowhere included in the pleadings in this case. Rather, Defendants can only refer to these selective details of their proposed products by relying upon limited excerpts of their ANDAs. As these excerpts of the ANDAs are not integral to the pleadings, Defendants' inclusion of these documents in their motion converts it to a motion for summary judgment.

two *Cumberland* cases, and contrary to Defendants' assertions, the '190 patent and '863 patent do not disavow any unclaimed solvents that otherwise meet the doctrine of equivalents, *and* there is a *disputed fact* as to whether Defendants' ANDA products are "covered by one or more claims of the '190 patent" and the '863 patent, as Cephalon alleges in its complaints.

**C. The Disclosure-Dedication Rule Does Not Preclude a Finding that Defendants Infringe the '190 Patent and/or the '863 Patent Under the Doctrine of Equivalents**

Knowing that the Court cannot resolve factual issues on a motion for judgment on the pleadings, or even summary judgment, Defendants attempt to recast the doctrine of equivalents as a *legal* issue, when it is undoubtedly *factual* in nature. Defendants allege that the disclosure-dedication rule, which was articulated in *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046 (Fed. Cir. 2002) (en banc), precludes a finding that Defendants infringe the '190 patent and the '863 patent under the doctrine of equivalents because the claims of those patents recite only the use of tertiary butyl alcohol as a solvent but the specifications for those patents disclose the use of other unclaimed solvents in discussing the invention. Defendants' reliance on the dedication-disclosure doctrine is misplaced.

Contrary to Defendants' assertion, *Johnson & Johnston* does not govern this case. *Johnson & Johnston* held only that a patentee may dedicate disclosed subject matter to the public "when a patentee discloses but *declines to claim [that] subject matter.*" 285 F.3d at 1054 (emphasis added). *Johnson & Johnston* explicitly held that the Supreme Court's governing decision in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950) ("*Graver Tank II*") made clear that a dedication does *not* occur where, as here, the patentee originally sought to claim or did in fact claim the subject matter elsewhere. *Johnson & Johnston*, 285 F.3d at 1053. Like the patentee in *Graver Tank II*, Cephalon originally sought claims to the equivalent solvents in its application for the patent-in-suit (here, the '190 patent). Specifically, original claims 20

and 21 of the application that issued as the '190 patent recited the solvents used by Defendants in their ANDA Products. (*Compare* Ex. A, Excerpt from Certified File History for '190 patent, at CEPH\_00001681 (original claims 20 and 21) *with* Ex. 3 to Defs. Br. (D.I. 59).) In contrast, the patentee in *Johnson & Johnston* never sought claims covering the alleged equivalent in that case.

Furthermore, Cephalon did, in fact, claim those solvents in another issued patent, which was filed as a continuation of the application that led to the '190 patent, and which shares the same specification as the '190 and '863 patents. (*See* Ex. B, U.S. Patent No. 8,461,350, at claim 1.) Under these circumstances, where Cephalon sought claims covering the equivalent solvents in the original application, and ultimately obtained claims covering those solvents in a related later-issued patent, there is clearly no dedication of the equivalent subject matter to the public. *See Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107 (Fed. Cir. 1996) (discussing *Graver Tank* and *Johnson & Johnston* and stating “by filing claims in the patent *application* that encompassed [the alleged equivalent] . . . , the patentee could not be said to have dedicated such an embodiment of the invention to the public”) (emphasis added).

Notably, the court in *Janssen Products, L.P. v. Lupin Ltd.*, Case No. 10-5954 (WHW), 2014 U.S. Dist. LEXIS 155248 (D.N.J. Mar. 12, 2014), rejected the defendant’s dedication argument when presented with facts similar to the situation here, even in the context of a motion for summary judgment. The patentee in *Janssen* initially filed a patent application for the patent-in-suit that included claims directed to the alleged equivalent. *Id.* at \*61. Those claims did not issue as part of the patent-in-suit and the narrower claims in the patent-in-suit did not literally cover the alleged equivalent. *Id.* The patentee in *Janssen*, however, filed a related application with claims that covered the alleged equivalent. *Id.* The *Janssen* court found that “the facts presented [were] more similar to those of *Graver Tank II* than those of *Johnson & Johnson*”

because the patentee in *Janssen* “sought claims on the alleged equivalent ... in its application for the patent-in-suit.” *Id.* at \*67–68. Thus, the *Janssen* court held, in circumstances nearly identical to here, that the dedication disclosure rule was inapplicable, and that summary judgment of non-infringement as a matter of law was improper.

Defendants do not, and cannot, cite any case applying the disclosure-dedication rule to facts similar to the facts in this case—i.e., where (1) the patentee sought claims encompassing the alleged equivalent during prosecution of one of the patents-in-suit, (2) those claims were subject to substantive examination during prosecution of that patent but did not issue as part of the patent, (3) the patentee sought claims reciting the alleged equivalents in a continuation application, and (4) the continuation application with claims reciting the alleged equivalents issued as a patent. Indeed, the disclosure-dedication rule does not apply here because Cephalon never dedicated to the public the use of solvents other than tertiary butyl alcohol in bendamustine hydrochloride compositions. *See, e.g., Janssen*, 2014 U.S. Dist. LEXIS 155248, at \*67–72; *Rosby Corp. v. Stoughton Trailers, Inc.*, Case No. 95-cv-0511, 2003 U.S. Dist. LEXIS 17034, at \*24–27 (N.D. Ill. Sept. 24, 2003) (rejecting defendant’s dedication argument when presented with facts similar to the situation here).

Like the patentee in *Graver Tank II* and *Janssen*—and unlike the patentee in *Johnson & Johnston* and the cases applying it—Cephalon “tried to claim” the alleged equivalents (i.e., the solvent systems used in Defendants’ ANDA products) in its application for the patent-in-suit (the ’190 patent). Like the patentee in *Graver Tank II* and *Janssen*—and again, unlike the patentee in *Johnson & Johnston*—Cephalon “fil[ed] claims in the patent **application** that encompassed [the alleged equivalent] ....” *Rosby*, 2003 U.S. Dist. LEXIS 17034, at \*25 (quoting *Maxwell*, 86 F.3d at 1107) (emphasis added by the court in *Rosby*). Thus, Cephalon did not disclaim any solvent

system described, but not expressly claimed, in the '190 patent and the '863 patent. Defendants' efforts to manufacture such an argument in order turn the *factual* infringement issue in this case into a pure legal issue must fail.

## **VI. CONCLUSION**

For the reasons stated above, this Court should deny Defendants' Rule 12(c) motion for judgment of non-infringement of U.S. Patent Nos. 8,436,190 and 8,609,863.



SHAW KELLER LLP

/s/ Karen E. Keller

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Stephanie E. O'Byrne (No. 4446)  
300 Delaware Ave., Suite 1120  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com

OF COUNSEL:

David M. Hashmall  
Calvin E. Wingfield Jr.  
Jonathan A. Auerbach  
Timothy J. Rousseau  
Joshua A. Whitehill  
GOODWIN PROCTER LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
(212) 813-8800

Paul F. Ware  
Daryl L. Wiesen  
Emily L. Rapalino  
Nicholas K. Mitrokostas  
GOODWIN PROCTER LLP  
Exchange Place  
53 State Street  
Boston, MA 02109  
(617) 570-1000

*Counsel for Plaintiff Cephalon, Inc.*

BAYARD, P.A.

/s/ Stephen B. Brauerman

Stephen B. Brauerman (No. 4952)  
Vanessa R. Tiradentes (No. 5398)  
Sara E. Bussiere (No. 5725)  
222 Delaware Avenue, Suite 900  
Wilmington, DE 19801  
(302) 655-5000  
sbrauerman@bayardlaw.com  
vtiradentes@bayardlaw.com  
sbussiere@bayardlaw.com

OF COUNSEL:

David M. Hashmall  
Calvin E. Wingfield Jr.  
Jonathan A. Auerbach  
Timothy J. Rousseau  
Joshua A. Whitehill  
GOODWIN PROCTER LLP  
The New York Times Building  
620 Eighth Avenue  
New York, NY 10018  
(212) 813-8800

Paul F. Ware  
Daryl L. Wiesen  
Emily L. Rapalino  
Nicholas K. Mitrokostas  
GOODWIN PROCTER LLP  
Exchange Place  
53 State Street  
Boston, MA 02109  
(617) 570-1000

*Counsel for Plaintiff Cephalon, Inc.*